SECTION 7

APR · 5 K950157

Q64XXX 510(K) SUMMARY

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. **Submitted By:**
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2. **Proprietary Name:**
Q64XXX Diagnostic Ultrasound System

Common/ Usual Name:
Diagnostic Ultrasound System with Accessories

Classification Name:
Ultrasonic Pulsed Doppler Imaging System (Product Code 90 IYN, 21 CFR 92.1550)

Diagnostic Ultrasonic Transducer:
(Product Code 90 ITX, 21 CFR 892.1570)

3. **Predicate Device:**

- Siemens Quantum™ 2000 Ultrasound System (K904019/A)
- Assorted Diagnostic Ultrasound Transducers (K904019/A)
- Siemens SONOLINE™ SI1200 Ultrasound System (K904564/A)

4. Device Description:

The Q64XXX is a general purpose, mobile, software-controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical values related to potential bioeffect mechanisms.. Its function is to acquire ultrasound data and display it in B-Mode, M-Mode, Color Flow Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, or in a combination of modes, on a CRT display .

The Q64XXX, has been designed to meet the following product safety standards:

- UL 544, Safety Requirements for Medical Equipment
- CSA 22.2 No. 601-1, Safety Requirements for Medical Equipment
- Standard for Real Time Display of Thermal and Mechanical Indices on Diagnostic Ultrasound Equipment, AIUM/NEMA, 1992.
- CE Mark and CB Certificate Certifying Compliance To:

  EN29001, Quality Systems

  EN46001, Quality Systems for Medical Device Manufacturers
- 89/336/EEC EMC Directive

  EN 50081-2, Electromagnetic Emissions Requirements

  EN 55011B, Group 1 = CISPR 11B, Group 1, RF Radiated/Conducted Emission Limits

  EN 50082-2, Electromagnetic Immunity Requirements

  IEC 801-2, Electrostatic Discharge Immunity

  IEC 801-3, Radiated RF Field Immunity

  IEC 801-4, Power Line Fast Transient/Burst Immunity
- 93/94/EEC Medical Devices Directive

  EN60601 = (IEC 601-1-1 + IEC 601-1-2), Safety and EMC Requirements for Medical Equipment

  CISPR11B, Group 1 = EN55011B, Group 1
  CISPR14, subclause 4.2 (clicks) = EN 55014, Intermittent Radiated RF Emissions Limits

  IEC 801-5 (draft), Power Line Surge Immunity

5. Intended Uses:

The Q64XXX ultrasound imaging system is intended for the following applications: General Radiology; Abdomen; Intraoperative; Small Parts; Transcranial; OB/GYN; Neonatal Cephalic; Urology; Vascular; Peripheral Vascular; Vascular Doppler.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

6. Technological Comparison to Predicate Device:

The Q64XXX is similar to the Quantum™ 2000 and the SONOLINE® SI1200 in that all three incorporate software controlled electronics to transmit ultrasonic pulses, via an applicator/transducer, into a patient, then receive return (echo) pulses and to convert those pulses into a visual display, to be used for diagnosis of various disease states. The operating principles of all three systems are the same. However, the Q64XXX incorporates an on-screen display of Mechanical (MI) and Thermal (TI) Indices, in compliance with the Standard for Real Time Display of Thermal and Mechanical Indices on Diagnostic Ultrasound Equipment, AIUM/NEMA, 1992.

END OF SECTION 7